

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 000004011PCT	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/JP2004/003662	International filing date (day/month/year) 18.03.2004	Priority date (day/month/year) 20.03.2003
International Patent Classification (IPC) or national classification and IPC		
Applicant EISAI CO., LTD.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising: a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows: <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items: <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☒ the international application as originally filed/furnished
- ☐ the description:
- pages _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the claims:
- nos. _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* _____ received by this Authority on _____
- nos.* _____ received by this Authority on _____
- ☐ the drawings:
- sheets _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 27-29

because:

☒ the said international application, or the said claims Nos. 27-29
relate to the following subject matter which does not require an international preliminary examination (*specify*):

The subject matter of claims 27 to 29 pertains to
a method for treatment of the human body by therapy
(PCT Rule 67.1(iv)).

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 27-29

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	5-18, 20	YES
	Claims	1-4, 19, 21-26	NO
Inventive step (IS)	Claims		YES
	Claims	1-26	NO
Industrial applicability (IA)	Claims	1-26	YES
	Claims		NO
2. Citations and explanations (Rule 70.7)			
Documents cited in the international search report:			
Document 1: James D. Lewis et al., "An Open-Label Trial of the PPAR Ligand Rosiglitazone for Active Ulcerative Colitis", The American Journal of Gastroenterology, Vol. 96, No. 12, pages 3323 to 3328, 2001			
Document 2: WO 02/100812 A (Eisai Co., Ltd.)			
Document 3: Hitoshi Asakura, "Tokuhassei Enshousei Choushikkan ni Taisuru Men'ekigakuteki Chiryouhou no Genjou", Igaku no Ayumi, Vol. 178, No. 9, pages 519 to 522, 1996			
Document 4: Akihiro Munekata et al., "Shuyousei Daichouen no Shindan to Naika Chiryou no Genjou", Igaku no Ayumi, Vol. 178, No. 9, pages 491 to 495, 1996			
Document 5: Tadao Baba et al., "Crohn-byou no Shindan to Chiryou no Genjou", Igaku no Ayumi, Vol. 178, No. 9, pages 496 to 501, 1996			
Document 1 indicates that a PPAR γ agonist and an aminosalicylic acid derivative, anti-inflammatory glucocorticoid, or an immunosuppressive compound are used together.			

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Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Therefore the invention set forth in claims 1 to 4, 19 and 21 to 26 of this international application lacks novelty and does not involve an inventive step in the light of document 1.

The use of specific compounds as a PPAR γ agonist is disclosed in the invention set forth in claims 5 to 9 of this international application, but these compounds are known as PPAR γ agonists, as set forth in document 2, and it would be obvious to a person skilled in the art to apply the compound set forth in document 2 as the PPAR γ agonist in the invention set forth in document 1.

Therefore the invention set forth in claims 5 to 9 of this international application is novel in relation to documents 1 and 2, but does not involve an inventive step.

In the invention set forth in claims 10 to 18 and 20 of this international application, specific substances are used as the aminosalicylic acid derivative, anti-inflammatory corticoid or immunosuppressor used in conjunction with the PPAR γ agonist, but documents 3 to 5 set forth treatment of inflammatory bowel disease such as ulcerative colitis or Crohn's disease, wherein sulfasalazine or mesalazine is used as the aminosalicylic acid derivative; prednisolone, betamethasone and butesonid are used as anti-inflammatory glucocorticoid; cyclosporine, azathioprine are used as immunosuppressors; anti-TNF α antibodies are used; and metronidazole is used as a compound having an anti-infection effect. Documents 3 to 5 also indicate that these medical agents are used

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Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

in combination, therefore it would be easy for a person skilled in the art to employ the medical agents set forth in these documents in an appropriate combination in the light of documents 3 to 5.

Therefore the invention set forth in claims 10 to 18 and 20 of this international application is novel in the light of documents 1 to 5, but does not involve an inventive step.